

Into the FUTURE

If ever there was a time when the pharmaceutical industry needed a strong set of hands to guide it, it is now. In an era of global recession, pipeline slowdowns, and safety scares, the choice of an experienced and thoughtful leader to guide the industry through these challenges and future opportunities is a priority.

In April, the Pharmaceutical Research and Manufacturers of America (PhRMA) elected AstraZeneca CEO David Brennan as its new chairman, a choice that bodes well for the future of healthcare and the pharmaceutical companies the organization represents.

In his more than three decades in the industry, Mr. Brennan has watched the companies he has worked for evolve and grow, and he has played a key role in moving some of those changes forward. He has been exposed to the complexities of an international industry, and he brings those global lessons to not only his company but the industry organization. He learned early on the value of medicine and the importance of acting honorably and with integrity. These are just a few of the many attributes he brings to his leadership roles at AstraZeneca and PhRMA.

Today, Mr. Brennan stands ready to meet the industry's challenges; in particular, he is eager to ensure the industry plays a central role in dealing with the pressing healthcare crisis the United States is facing. And he is calling on his colleagues in the industry to do likewise.

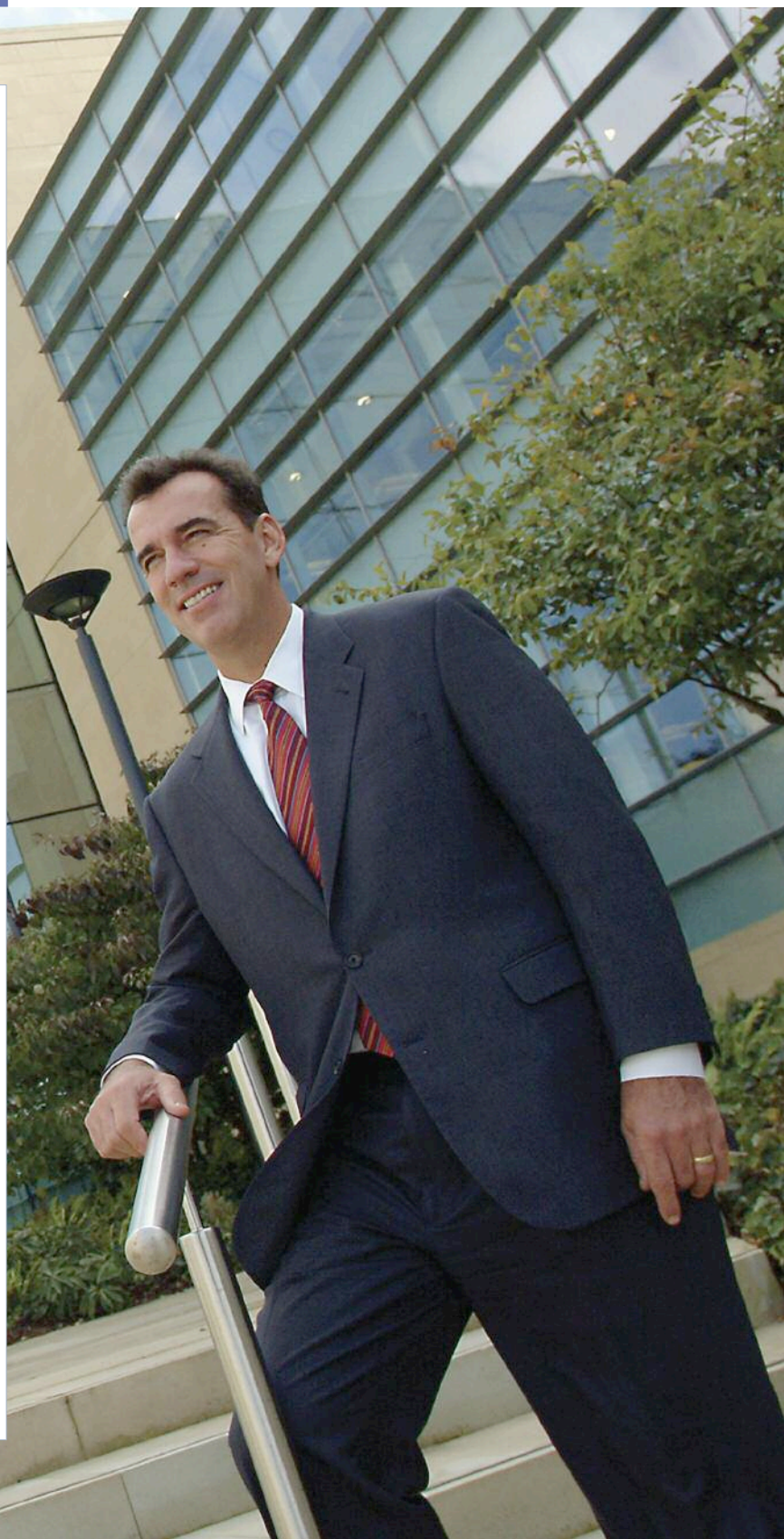
"There seems to be a very strong commitment on behalf of the current administration, as well as Congress, for healthcare reform, and the industry will need to adapt to be able to make the expected contributions," he says. "By that I mean we need to bring true innovation to the healthcare system; we need to make sure the products we bring to the market represent breakthrough therapies; and we have to make sure we are able to operate in, what I would expect will be, a changed healthcare landscape."

Mr. Brennan says he envisions a time in the not-too-distant future when all people in need are diagnosed and treated, fewer patients are hospitalized, and medicines will be seen not as the cost of sickness, but as an investment in improving health.

"I came to this industry almost 34 years ago, motivated by the challenge of improving human health," he says. "Every day, our medicines improve people's lives, especially the lives of those afflicted with serious, highly prevalent diseases such as cancer. Now, with the potential for the right kind of healthcare reform, we may soon be able to help even more people."

Industry leaders, he says, must ensure they maintain a strong position as proponents for healthcare improvements.

"As comprehensive healthcare policy reform is considered, there



Taking the helm of PhRMA at a difficult time for the pharmaceutical industry, AstraZeneca's CEO David Brennan has set the organization on a collaborative course aimed at ensuring the healthcare landscape benefits patients and protects innovators.

is an opportunity for PhRMA to ensure that those who are considering policy change know that it's very important to have a strong pharmaceutical industry," he says.

For example, he notes President Obama's commitment, made during his State of the Union address, to see cancer cured.

"To develop a cure for cancer, it's important to ensure that the healthcare system has a strong pharmaceutical industry, one that's focused on innovation, one that is rewarded for innovation when we're successful, one that can work with academia, one that can work with the NIH, and one that can work with a strong, well-funded FDA to get products approved," Mr. Brennan says.

"We have an important role to play because no one else can develop drugs," he continues. "Researchers in academia and the NIH can develop targets, and they can get early breaks in science, but the pharmaceutical industry is uniquely positioned to translate that science into medicines that can potentially accomplish President Obama's goal."

PREPARING FOR CHANGE

Over the past few years, the industry has gone through some major changes, with pipeline slowdowns and patent expirations, a host of huge M&As, pressure from the Food and Drug Administration on improved safety controls, and most recently a global recession that has impacted all industries.

The fallout from the recession will inevitably heavily impact healthcare, Mr. Brennan says.

During his speech to PhRMA in April when he was elected chairman, Mr. Brennan noted the impact of job losses.

"Since the onset of this downturn in the United States alone, more than 4.4 million people have lost their jobs and, in many instances, they've also lost their health insurance," he said in his address. "It's not hyperbole to say before this recession is over, millions more will join the 47 million other Americans who do not have health insurance."

The effect of these job losses is that overcrowded hospital emergency rooms will face even greater burdens, and for those who are still insured, premiums inevitably will rise.

"As we move forward with healthcare

reform, we've got to make sure that we get it right this time," he said in his address. "I'm in full agreement with President Obama that we need reform that's built on American traditions to meet the diverse medical needs of our people, while we're reducing cost and strengthening the economy." (For the full transcript of Mr. Brennan's PhRMA address, see the digital edition of PharmaVOICE.)

But healthcare reform isn't the only issue the industry has to face. One huge change in recent years has been salesforce cutbacks, which have led to insecurity for many industry employees. Mr. Brennan says it is important to focus on the self-esteem of all employees in uncertain times.



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"The reductions in salesforces will have an impact on morale," he says. "When people see this happening in other companies, they worry that it will happen in theirs. One of the challenges for management is to be open and honest with people about what those opportunities for the future really represent."

Certainly, the changes in the industry will likely be felt at AstraZeneca as they have elsewhere.

"In the future, I would expect we'll have fewer salespeople than we had a few years ago, but that will vary based on the product opportunities that we have," Mr. Brennan says.

Many in the industry have talked about the opportunities e-detailing and Internet outreach have to offer, but Mr. Brennan remains guarded about technology as a replacement for human contact.

"There are certainly opportunities through the use of technology these days to interact with customers differently; we already do some of this in the United States and in some other

markets around the world," he says. "Technology solutions work in certain segments of the market, but they haven't become a replacement for personal selling; they are supplemental alternatives in certain regions."

Mr. Brennan believes personal selling in some form will continue to be at the heart of much of AstraZeneca's commercial activities, though he admits some of the strategies might change a little bit.

"Personal selling will continue to be a centerpiece of commercial activity for companies like ours, both in the primary-care and in the specialty markets," he says.

Another important change in the industry has been the growing emphasis on partnerships. Industrywide, pharmaceutical companies have been working with other pharma companies, biotech companies, and academic institutions to uncover the brightest and best ideas for product development.

This increased willingness over the past few years by large pharmaceutical companies to access leading science that is taking place outside of their own labs has huge potential for future research, Mr. Brennan believes.

"Since 2006, AstraZeneca has built its bio-

logics capabilities through two acquisitions and signed more than 20 major deals with outside partners," he says. "We also partner with academic institutions to share knowledge and spur new ideas. A partnership approach can create value for the organizations involved and drive innovative advances that ultimately benefit patients."

Nevertheless, the difficulties of bringing a product to market continue to be a problem for the industry and patients alike.

"The magnitude of unmet patient need is never lost on me," Mr. Brennan says. "The daily tasks — from business meetings and international flights to scientific debates and an unending stream of clinical data — never diminish the fact that millions of people rely on our industry to tirelessly press forward in search of new medicines. The biopharmaceutical industry is unique because it has the ability to bring medicines from the laboratory to the patient in a consistent, systematic way. But the process of bringing a new medicine from discovery to market requires eight to 12 years, so we must continue to improve our speed and quality, while managing pricing pressures and



“As we move forward with healthcare reform, we’ve got to make sure that we get it right this time.”

challenges to our intellectual property, for example.”

A FRESH OUTLOOK

Early in his career, Mr. Brennan learned the importance of integrity and ethics in business, thanks to a good mentor.

“My first district manager was a man of

tremendous integrity,” he says. “He helped me understand the importance of adhering to one’s values and operating properly in an environment where, because of the nature of sales, one can frequently encounter circumstances that might go against one’s conscience. That was an important lesson that I’ve kept with me throughout my career.”

As AstraZeneca’s CEO, Mr. Brennan is well aware that leadership starts at the top and that people in a large organization look to their CEO to reinforce the messages around values and to demonstrate behaviors that are expected throughout the company.

“When we talk about having a company

THE MAKINGS OF A LEADER

From the moment he left college, David Brennan, CEO of AstraZeneca, has been with the pharmaceutical industry. He had been drawn to sales and interacting with customers from an early age, having been a paperboy from the age of 11.

But it was his brother, a medicinal chemist, who suggested that the pharmaceutical industry might be an area of interest.

“My brother had spent some time in the industry working toward his Ph.D. and told me that it was a great industry to work in, and that was where my career began,” he says. “I was fortunate to be offered a position in sales at Merck.”

It wasn’t long before Mr. Brennan’s passion for what the industry does was awakened.

“I remember being out in the field and we had just introduced a couple of new innovative products,” he says. “While speaking to physicians who were using these products, I quickly gained an appreciation for how much of a difference these products were making in patients’ lives. They told me that I should be proud of what the company did.

“It was then that I began to gain an appreciation for the true value that pharmaceutical companies can offer when we bring products to the market that make a big difference to people’s lives,” he continues.

His natural ability to work with others meant Mr. Brennan truly enjoyed his time in sales.

“I enjoyed being out in the marketplace

with customers and learning how to properly and appropriately position products,” he says.

Mr. Brennan also worked in sales management and marketing in the United States before moving to the international division, where he worked in sales training and marketing. He later ran the international training group.

“I always enjoyed the training department, because we worked specifically in marketing and sales training internationally,” he says. “This was an opportunity to work in a number of different countries. It was also an opportunity to work with the local management teams to raise the standards of operations, from a management perspective, from a selling capability perspective, or from a marketing perspective.”

These experiences opened his eyes to the differences in the way each country operates.

“The cultural experience is extremely relevant in the pharmaceutical setting,” he says. “The cultural differences, from country to country and from healthcare system to healthcare system, impact how a company operates locally. These insights gave me a taste of how the company operated throughout the world.”

Ultimately, Mr. Brennan rose to be general manager of Chibret International, a French subsidiary of Merck that specializes in ophthalmic products, before embarking on a new chapter that gave him further insight into running an organization.

There had been a longstanding agreement between Merck and what was then Astra to form a joint venture and, in 1992, that organization was launched as AstraMerck.

A small group of executives was selected to

get the business started, among them was Mr. Brennan.

“I left a very structured, large organization at Merck to become one of six people in the newly formed company,” he says. “I had worked with the general manager earlier in my career, and he selected a handful of us to help him start the business.”

Mr. Brennan was responsible for business planning and development at the new organization.

“We started from scratch; we spent about two years building the business,” Mr. Brennan continues. “We marketed a couple of the products for Astra in the United States, and then those products were transferred over to Astra Pharmaceuticals. Over the course of the next several years, we grew from a \$360 million company to one that had almost \$4 billion in sales. We expanded from the original six employees to about 4,000. This was quite a ride.”

This experience was one that culminated in Mr. Brennan taking the helm at what became AstraZeneca after the merger between Astra AB and Zeneca Group.

Certainly, he couldn’t have known at the time where the job would lead, but he knew it was an exciting opportunity.

“I had enormous respect for the people who were involved in the venture and recognized the potential to work with people who would pull in the same direction on important issues,” he says.

“Once you’re involved in an endeavor like that, you get an appreciation for what’s possible,” he says.



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that values diversity, when we talk about a company that operates openly and honestly, and when we talk about a company that has integrity, it's my job to demonstrate these behaviors so our people understand these aren't just words on a piece of paper; these are core principles that we are serious about,” he says.

For example, Mr. Brennan says positive employee engagement is key to enabling people to maximize their talents and contributions to the business.

“Feedback opportunities are integrated into our internal communications programs, and

we offer a confidential hotline for employees to raise concerns,” he says. “We also use a global employee survey to track employee opinions across a range of key topic areas. These anonymous surveys provide valuable insights for business leaders and managers about what we are doing well and where improvements need to be made. These insights are also used to inform strategic planning across the business.”

To further ensure employees are kept in the loop, during 2008 members of the senior executive team held dialogue sessions with employees at a number of AstraZeneca locations to discuss in detail the company's strategy for managing the challenges and opportunities the business currently faces.

These sessions took place in China, Japan, Italy, Germany, France, the United Kingdom, Sweden, the United States, and Canada and involved more than 1,700 employees from all disciplines, Mr. Brennan explains. Some of the sessions were also Web-streamed on the company's intranet, making them available to all employees.

“We are committed to promoting and

maintaining a culture of respect and equal opportunity in which all decisions about recruitment, hiring, compensation, development, and promotion are made solely on the basis of a person's ability, experience, behavior, work performance, and demonstrated potential,” he says. “Every manager is responsible for implementing this requirement.”

Going forward, Mr. Brennan believes the company's future is strong. AstraZeneca filed two new drug applications in 2008 and has the potential to file up to four in 2009.

“Those applications represent the culmination of a tremendous amount of work by our research and development organization,” he says. “Hopefully, we will have some new products to bring to the market and show we bring benefits to the healthcare system.”

Of the two products filed in 2008, the FDA has requested more data on one. While Mr. Brennan expects the company will deliver those data this year, he doesn't expect to hear back on the review process until next year.

The other product is Onglyza for the treatment of adults with Type 2 diabetes, for which AstraZeneca has a license agreement with Bristol-Myers Squibb. In early April, the FDA's Endocrinologic and Metabolic Drugs Advisory Committee determined (by a vote of 10 to 2) that the data supporting the new drug application for Onglyza (saxagliptin) were sufficient to rule out unacceptable cardiovascular risk relative to comparators in the program.

The advisory committee unanimously recommended that the sponsors perform a post-marketing trial to confirm the cardiovascular profile of Onglyza. AstraZeneca and Bristol-Myers Squibb are working on a series of Phase IIIb and IV studies, including a large, controlled, randomized postmarketing trial to further characterize the long-term clinical effectiveness, as well as the cardiovascular profile of Onglyza. The companies will now work with the FDA to finalize the postmarketing trial design.

“This product, if approved, would be entering a market that continues to grow, and there are huge advantages for Onglyza, particularly in the area of safety,” Mr. Brennan says. ♦

LEADERSHIP CREDENTIALS

DAVID BRENNAN – RESUME

JANUARY 2006 – PRESENT. CEO, AstraZeneca Plc., and Executive Director of AstraZeneca since March 2005.

2005 – 2006. President and CEO of AstraZeneca Pharmaceuticals LP (which does business as AstraZeneca U.S.), with responsibility for all operations in the United States

2001 – 2005. Executive VP, North America Division, AstraZeneca Plc.

1999 – 2001. Senior VP, Commercial Operations, AstraZeneca Pharmaceuticals LP

1992 – 1999. VP of Marketing, Business Planning and Development Astra Merck Inc., and then Astra Pharmaceuticals LP

1990 – 1992. General Manager of Chibret International, France (a subsidiary of Merck & Co. Inc.) Sales Representative, Merck

EDUCATION

Bachelor of Arts in Business Administration, Gettysburg College

BOARD MEMBERSHIPS

2009. Chairman, Pharmaceutical Research and Manufacturers of America (PhRMA)

JULY 2001 – PRESENT. Member of Executive Board, PhRMA; Treasurer, PhRMA; Board member of the Chief Executive Officer Roundtable on Cancer; Board Member of the European Federation for Pharmaceutical Industries and Associations (EFPIA); Chairman of the Board for the Southeastern Pennsylvania Chapter of the American Heart Association

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BY KIM RIBBINK



Healthcare Reform: GETTING IT RIGHT

A Kaiser Family Foundation study shows that in 1970, U.S. healthcare spending stood at a modest \$365 per resident, or 7.2% of GDP. But by 2016 healthcare spending is forecast to rise to well more than \$12,000 per U.S. resident. That's an unbelievable and unsustainable 19.6% of GDP.

In early April 2009, David Brennan, CEO of AstraZeneca, was elected chairman of PhRMA. The following is the main body of his speech to his colleagues on the day he took office.

"... Today there's a crisis going on. We are in the midst of a deepening global economic recession. Since the onset of this downturn in the United States alone, more than 4.4 million people have lost their jobs and, in many instances, they've also lost their health insurance. It's not hyperbole to say that before this recession is over, millions more will join the 47 million other Americans who do not have health insurance.

So, what's the cost of this lack of proper health insurance? For one thing, more people who don't have the ability to pay will crowd already overtaxed hospital emergency rooms. Everybody's premiums will rise. And without routine access to a physician and to preventive care there will most likely be an increase in the prevalence of the chronic diseases — like diabetes — that now claim up to 75 cents of every healthcare dollar spent in the United States.

And as if that wasn't enough, Medicaid and Medicare costs continue to soar as ballooning healthcare costs touch just about every American household. A Kaiser Family Foundation study shows that in 1970, U.S. healthcare spending stood at a modest \$365 per resident, or 7.2% of GDP. But by 2016, healthcare spending is

forecast to rise to well more than \$12,000 per U.S. resident. That's an unbelievable and unsustainable 19.6% of GDP.

Today, everybody is worried about this immediate economic crisis, but the cost of healthcare has been undermining the financial soundness of the nation for a long time.

From Main Street to Capitol Hill, people are clamoring for change. Elected officials and policymakers from both sides of the aisle are discussing — and, of course, debating — their visions of healthcare reform.

So the crisis in American health and healthcare and the need for change now is a headline story. As we move forward with healthcare reform, we've got to make sure that this time we get it right.

I'm in full agreement with President Obama that we need reform that's built on American traditions to meet the diverse medical needs of our people, while we're reducing cost and strengthening the economy. Americans deserve a system that provides every man, woman, and child with a consistent level of care. I'm talking about a system that helps them live healthier and live longer.

We — the members of PhRMA and our partners across healthcare and every sector — want to do all that we can to play an active role in building meaningful solutions. As we promote better healthcare for patients and their families, it's easy to move into a white hat/black hat, us-versus-them world view.

We can't afford to do that anymore. And, most importantly, sick patients certainly can't afford for us to do that.

“But innovation without delivery doesn’t help the patient. With that in mind, the PhRMA-led Partnership for Prescription Assistance — in alliance with 1,300 national state and local partners — brings Americans in need access to medicines.”

So, with the goal of healthcare reform, we’ve got to work together in a new way where we respect our differences and understand we all are facing real change. If we can genuinely do that, we open the door to more powerful and inventive collaborations. And do you know what? I think we’re succeeding.

Some partners — who are with us for the first time at our annual meeting — were until recently absolute critics of the industry. For years they used their resources to criticize us, while at times we battled them. But today I’m glad to say we’re connecting around the need to reform a broken system.

Innovation without delivery doesn’t help the patient. With that in mind, the PhRMA-led Partnership for Prescription Assistance (PPA) — in alliance with 1,300 national state and local partners — brings Americans in need access to medicines.

IDEAS NOT IDEOLOGY

As we develop proposals at PhRMA, we need to recognize, and on occasion remind ourselves, that we don’t have all the answers. We have to listen carefully to our partners and others seated around the table. We want deliberations dominated by ideas, not by ideology.

Americans deserve a debate that features fresh thinking and open-mindedness, not partisan bickering. Only respectful, give-and-take discussions will produce the reforms we need. I look forward to actively participating in many more of these discussions.

So what needs to be at the center of the healthcare reform debate? First, we’ve got to have quality care with an emphasis on outcomes. We also have to reduce healthcare disparities. And, as an example, we should explore opportunities to increase racial and ethnic diversity in clinical trials.

Next, we’ve got to preserve what is good about the current system. And, in my view, that includes the strong relationship between physician and patient. Without access to prevention information — and the counsel that comes from routine visits to a physician — Americans without health insurance are more likely to die of cancer and other chronic diseases. Prevention and access are not just about a pill.



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Yet, even with a doctor’s best counsel and lifestyle changes, we won’t stem the tide of chronic disease. We need the right medicines for the right patient at the right time. We want to make sure that the uninsured and the underinsured both have sufficient access and coverage. And that coverage needs to include a comprehensive prescription drug benefit.

Our challenge is to expand our pipelines of valued medicines that make a meaningful difference in patients’ lives. That’s the most important step we can take in fighting chronic disease.

Studies show that newer medicines reduced hospital and other non-drug costs. For each additional dollar spent on newer pharmaceuticals, more than \$6 is saved in total healthcare spending. And more than four of those dollars come from savings in spending on hospital stays.

PPA is clearly very important. But it’s no substitute for having comprehensive healthcare that provides every American with a real, affordable opportunity to get the innovative medicines they need.

President Obama noted that medical costs have gone up four times faster than wages.

Yet, as other healthcare costs spiral, medicines have remained at about the same percentage of the healthcare dollar for 40 years. That’s the good news.

The bad news is that insured patients are forced to pay considerably higher percentage copays on medicines than on what they pay for other healthcare services.

I’m an advocate of free-market-based healthcare solutions. But, within that framework, I support appropriate government

efforts to protect people whose healthcare needs aren’t met by the private marketplace.

That’s exactly what the pharma industry does with the prescription savings program. I also agree that standard insurance coverage can be improved. Quite frankly, Americans deserve copay reform. The current skew of the standard insurance benefits clearly penalizes patients for the use of the more innovative medicines.

Several companies are learning the benefits of copay reform.

Pitney Bowes, for instance, reduced copayments for drugs prescribed for diabetes and asthma. The Wall Street Journal reported that the company realized a \$1 million net savings in the first year by reducing complications common to those diseases.

Some health insurers are also getting it.

And this kind of innovation on the part of payers provides the incentive for innovators to bring high-value medicines to market. Wouldn’t it be great if this outcome-based approach became standard practice?

In the midst of these challenges we — with a growing list of partners — have achieved real progress in promoting healthcare reforms that benefit tens of millions of people.

Recently, 4.1 million previously uninsured, low-income children gained access to healthcare under the State Children’s Health Insurance Program, otherwise known as SCHIP. PhRMA was proud to support SCHIP’s reauthorization and expansion. With SCHIP in play, millions of children gain access to affordable healthcare and are less likely to be touched by chronic diseases that increase costs and short-circuit their potential.

David Brennan

KEY ACTIONS TO ACHIEVE REFORM THAT BENEFIT PATIENTS AND REDUCE COSTS

- 1 Promote quality care for all, with an emphasis on outcomes.
- 2 Embrace a system that supports a doctor/patient relationship and emphasizes prevention and personal responsibility.
- 3 Bring about copay reform that gives patients real access to the best medicines and treatments.
- 4 Work toward policies that promote continuous medical innovation.
- 5 Be advocates for strengthening the FDA so that they can do a more timely and consistent job.

Mr. Brennan says for all of this to happen collaboration is key. "We need to partner differently and act differently than we have in the past," he says. "Whether in the development of new medicines or promoting existing products, partnerships are essential. And they're no less important in promoting comprehensive healthcare reform."

At the other end of the age spectrum, another PhRMA-supported bill, Medicare Part D, was enacted more than five years ago.

Before Medicare Part D came in, an estimated 30% to 40% of Americans older than 65 had no drug coverage. Now, more than 90% of those eligible for Medicare use the comprehensive prescription plan.

The Wall Street Journal and other polls show that satisfaction levels continue to approach upwards of 90% among older adults using the plan.

And as the Medicare Part D participants gain the benefit, American taxpayers save money. The Congressional Budget Office has reduced its previous 10-year expense forecast for the program by \$438 billion, or 37%. That's a big savings.

When was the last time a government program achieved a high satisfaction rate and came in several hundred billion dollars below projected costs?

Both SCHIP and Medicare Part D had opposition from folks with whom we've



worked on other issues. I appreciate their concerns. But as these programs promote better health, they can also save patients and taxpayers money. Not a bad combination!

In his speech to Congress, President Obama called for our nation to find a cure for cancer. We applaud him for that. We, too, want to move closer to that goal. But we can't get far down that road without continued world-class innovation.

And, you know what? Our industry can't get there without the government. And, the government won't get there without us. Quite frankly, we need each other.

Tripling the funding to the National Institutes for Health or the National Cancer Institute would give Americans some early-stage victories.

But that's not going to cure the spectrum of diseases known as cancer. While the government assists with research, the biopharmaceutical industry has the ability to bring medicines from the laboratory to the patient in a consistent, systematic way.

Over the last 25 years, we've come a long way in the war on cancer. But contrary to the Hollywood-like scenarios, our battle with cancer isn't so much about spectacular breakthroughs as it is about steady, incremental progress.

Innovative, incremental improvements have brought tremendous benefits to mil-

“We need an environment that includes strong, well-defined intellectual property rights; a productive NIH; a robust research-based and patient-driven pharmaceutical industry whose products can move more efficiently from the laboratory to the patient; and a strong, well-functioning FDA.”

lions of cancer patients and their families as medicines extend and increase the quality of life.

In 30 years, with better screening and treatments, we've improved the cancer survival rate from one-half of those diagnosed to two-thirds. And some diseases, such as breast and prostate cancer, now have about 90% or better survival rates.

Maybe we can cure cancer.

But, even if we don't, our scientists tell us that we're moving toward making it a treatable chronic disease, a condition like arthritis that can be managed — a disease that you can live with — rather than die from.

Achieving that goal even faster and creating sustainable healthcare reform requires policies that are more conducive to the medical innovation that is the genesis and cornerstone of our industry.

GETTING IT DONE

So what needs to be done? We need an environment that includes strong, well-defined intellectual property rights; a productive NIH; a robust research-based and patient-driven pharmaceutical industry whose products can move more efficiently from the laboratory to the patient; and a strong, well-functioning FDA.

These are all essential, if we are going to find cures for dreaded diseases and meet the other unmet treatment needs of people everywhere.

Now, what do I mean by a “strong, well-functioning FDA”?

Clearly, it’s doing better than a decade ago, but an understaffed and underfunded FDA is an agency in crisis. In 2008, the FDA missed more than 50 PDUFA goal application review dates.

Who pays the cost of those delays? Yes, they impact individual companies, but it’s the patient waiting for the next critical medical advance who pays the highest price.

So, what are we — the members of PhRMA — doing about it?

We’re working hard for increased appropriations to the FDA so that it is recognized as a watchdog with a full set of teeth — an agency with the technology and people it needs to do a more timely and consistent job in regulating us and bringing innovative treatments to patients.

A GLOBAL AGENDA

As we debate in America medical innovation’s importance, other nations are developing policies to expand their role. When I took my first job in the pharmaceutical industry, Europe was seen to be the world pharmaceutical leader.

Most of my pharma colleagues older than 40 know the rest of the story. With governments constraining patient access to new medicines, investment returns shrank and a segment of Europe’s pharma-base shifted to the United States.

Today, both the European Union and individual nations are working to institute pro-medical innovation policies to try to recapture Europe’s leadership in this industry. For example, Great Britain has started to put less intru-

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sive and more predictable policies in place that open the door to enabling and rewarding innovation.

In Asia, countries are rolling out medical innovation strategies. China in particular is moving to create a better environment for innovation, and investing in it. The Chinese are taking the long view as they invest large sums of government money. They are creating strategies to develop the infrastructure and biochemistry knowledge in their people that will make them more competitive over the next 20 to 40 years.

Today, the United States leads the world in creating new medicines, and we’ve got to make sure that this drive for innovation continues. Last year, U.S. pharma spent \$65 billion on R&D. And in 2006, the overall biopharmaceutical sector added \$88 billion to the U.S. GDP.

And then there are the jobs. More than 3.2 million people’s jobs have ties to our industry.

We have an important economic impact on the nation.

But, in addition to that, our citizens should be among the first in the world to gain access to new, often life-saving medicines.

Quite frankly, without a pipeline full of innovative medicines, it will be difficult, if not impossible, to create meaningful and sustainable healthcare reform.

At the end of the day, I think it’s safe to say that every one in this room wants significant healthcare reform.

PARTNERSHIP FOR REFORM

In every partnership, alliance, or coalition that PhRMA enters, the common denominator has to be support for improving patient care and delivering life-enhancing medicines. With that goal in mind and as economic turmoil deepens and the healthcare crisis touches more people, our coalitions expand.

Through actively working in partnerships and coalitions, we are making progress and continuing to learn from one another.

We don’t and won’t agree on everything. Some might even shake their heads when they’re reviewing the broad assortment of individuals and organizations that have joined together under our healthcare reform umbrella.

But the fact is, our goal is quite clear: better, more cost-efficient, and less costly healthcare for families.

With the goal of sharing ideas and gaining access to new perspectives, I’ll soon be on the road crisscrossing the United States, meeting with policymakers and opinion-leaders, elected officials, and others, including patients and healthcare professionals of every stripe.

From this trip and others that follow, I intend to stay in touch with what’s going on at the grassroots level and on Pennsylvania Avenue.

I came to this industry more than 33 years ago. I was motivated by the challenge of improving human health and saw I could be part of a business that contributes something real to society. We do that.

Every day, our medicines improve people’s lives, especially the lives of those afflicted with serious, highly prevalent diseases like cancer. Now, with the potential for the right kind of healthcare reform, we may soon help even more people.

It is a good time for PhRMA.

There’s no doubt: we have the challenge of recession, but current healthcare debates give us the opportunity to make our case — and to make it very publicly.

We start the discussion with stronger business codes and a renewed emphasis on transparency.

This will serve us well and make us a stronger, better partner in the healthcare debates ahead.

Working together with partners and advisors from every sector and every walk of life, we can — and I believe this time we will — get the right healthcare reform. I envision a time not all that far away when all people in need are diagnosed and treated. Fewer are hospitalized. And medicines will be seen not as the cost of sickness, but as an investment in improving health.

Together, we will make that happen. ♦